

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/465,054	12/16/1999	DAVID BURTON	990326.ORI	8408
7590 11/01/2005			EXAMINER	
John F. Klos			PATEL, MITAL B	
Fulbright & Jav				
80 South 8th Street			ART UNIT	PAPER NUMBER
Suite 2100			3743	-
Minneapolis, N	MN 55402		DATE MAILED: 11/01/2009	5

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	09/465,054	BURTON, DAVID
Office Action Summary	Examiner	Art Unit
	Mital B. Patel	3743
The MAILING DATE of this communication a Period for Reply	ppears on the cover she	et with the correspondence address
A SHORTENED STATUTORY PERIOD FOR REF WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory perior. - Failure to reply within the set or extended period for reply will, by stat Any reply received by the Office later than three months after the ma earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMN 1.136(a). In no event, however, in ad will apply and will expire SIX (foute, cause the application to become	UNICATION. nay a reply be timely filed) MONTHS from the mailing date of this communication. me ABANDONED (35 U.S.C. § 133).
Status		
1)⊠ Responsive to communication(s) filed on 30	September 2005.	
2a) ☐ This action is FINAL . 2b) ☑ Ti	nis action is non-final.	
3) Since this application is in condition for allow	vance except for formal	matters, prosecution as to the merits is
closed in accordance with the practice unde	r <i>Ex parte Quayle</i> , 1935	C.D. 11, 453 O.G. 213.
Disposition of Claims		
4)⊠ Claim(s) <u>32 and 57-83</u> is/are pending in the	application.	
4a) Of the above claim(s) is/are withd		1.
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>32,57-83</u> is/are rejected.		
7) Claim(s) is/are objected to.		•
8) Claim(s) are subject to restriction and	I/or election requiremer	t.
Application Papers		
9)☐ The specification is objected to by the Exami	ner.	•
10)☐ The drawing(s) filed on is/are: a)☐ a		d to by the Examiner.
Applicant may not request that any objection to t	ne drawing(s) be held in a	peyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the corr	ection is required if the dra	wing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the	Examiner. Note the atta	ched Office Action or form PTO-152.
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for forei a) All b) Some * c) None of:	gn priority under 35 U.S	s.C. § 119(a)-(d) or (f).
1. Certified copies of the priority docume	ents have been received	
2. Certified copies of the priority docume		
3.☐ Copies of the certified copies of the pa		
application from the International Bure	<u>*</u>	-
* See the attached detailed Office action for a l	* * * * * * * * * * * * * * * * * * * *	
	•	
Attachment(s)		
1) Notice of References Cited (PTO-892)	4) ☐ Inter	view Summary (PTO-413)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Pape	r No(s)/Mail Date
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date	08) 5) ∐ Noti 6) ☐ Othe	e of Informal Patent Application (PTO-152)
U.S. Patent and Trademark Office		
	Action Summary	Part of Paper No./Mail Date 10302005

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/30/05 has been entered.

Response to Amendment/Arguments

- 2. Applicant's arguments filed 9/30/05 have been fully considered but they are not persuasive.
- 3. In response to Applicant's arguments that Miles fails to specifically teach connection of the sensors to a headgear, it should be noted that Miles does disclose that sensors may be mounted inside the mask or connected to the mask. Since connected to the mask is such a broad disclosure and leaves open the possibility of connection to the mask via various means including but not limited to a headgear.
- 4. In response to Applicant's arguments regarding Brown, it should be noted that the Examiner is relying on the Brown reference for the teaching of a headgear having mounted thereon sensors. The Examiner is not relying on the Brown reference for a teaching of EEG sensors. As such, Applicant's arguments with respect to Brown are rendered moot.

Application/Control Number: 09/465,054 Page 3

Art Unit: 3743

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

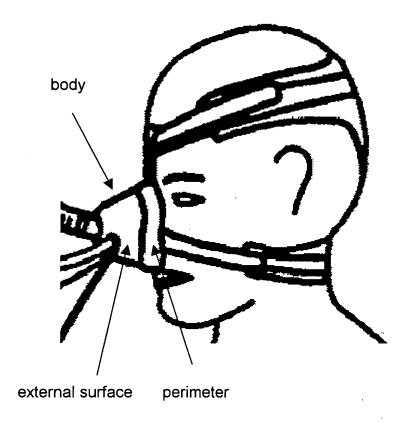
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 7. Claims 32, 57-61, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles (US 5,353,788) in view of Brown (US 6,000,395).
- 8. As to claim 32, Miles teaches a breathing mask 3,26 for monitoring a patient during gas delivery comprising a body (See Fig. 2 attachment below) having an internal surface (inherent from Fig. 2 attachment below since mask is shown to be cupping the nose), an external surface (See Fig. 2 attachment below), and a perimeter surface (See Fig. 2 attachment below) shaped to form a seal around the patient's nose; and at least one EEG sensor (See Col. 4, lines 33-35; lines 44-45; lines 55-59; Col. 5, lines 6-15; and Col. 7, lines 37-51 which disclose a plurality and variety of sensors including an EEG sensor and further teach that the

Art Unit: 3743

sensors may be mounted inside the mask or connected to the mask thereby reading on the limitation "extended from the mask"; it should also be noted that the physiological specific sensor is located on the respective/corresponding anatomy as shown in Fig. 2 and therefore, it would be obvious to one of ordinary skill in the art to place an EEG, which inherently measures/detects brain activity near or on the head and away from the mask in order to get a more precise reading) extended from the mask and positioned to detect brain activity. Miles teaches essentially all of the limitations except for a headgear adapted to retain the body on the patient's head, the headgear having at least one EEG sensor positioned thereon. Brown teaches the use of a headgear with sensors placed strategically thereon so that the particular bodily condition of the user may be sensed. Therefore, it would have been obvious to one of ordinary skill in the art to provide a headgear in the breathing mask of Miles so that specific body sensors such as an EEG sensor may be placed strategically on the appropriate anatomy of the human being to sense that specific bodily condition as taught by Brown. Furthermore, it would have been obvious to one of ordinary skill in the art that an EEG sensor be placed on or near the head to detect the appropriate signal and as such it would have been further motivation to provide the EEG sensor on a headgear type device to hold the sensors in place in conjunction with the mask.

Art Unit: 3743



- 9. **As to claim 57**, the above combination teaches a breathing mask wherein the headgear is a cap (It should be noted that Brown teaches a headgear that is a cap).
- 10. As to claim 58, the above combination teaches essentially all of the limitations except for wherein the perimeter surface is adapted to detect ECG. Miles does teach an ECG lead 6 (See Fig. 2) placed over a patient's heart/chest area. However, it should be noted that Miles also teaches that some of the sensors may be mounted inside or connected to the mask (See Col. 4, lines 44-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including one that detects ECG, may be placed

Art Unit: 3743

inside the mask or connected to the mask (a perimeter surface is encompassed by the disclosure) to provide an alternative placement of the sensor.

- 11. As to claim 59, the above combination teaches essentially all of the limitations except for further comprising a flow sensor connected to the internal surface. Miles does teach an airflow sensor (See Col. 4, lines 33-35 and Col. 5, lines 20-21). It should be noted that in Col. 5, lines 20-21, Miles teaches a flow sensor contained within the CPAP device; however, Miles also teaches that some of the sensors may be mounted inside or connected to the mask (See Col. 4, lines 44-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including a flow sensor, may be placed inside the mask or connected to the mask thereby providing an alternative placement of the sensor.
- 12. **As to claim 60**, the above combination teaches essentially all of the limitations except for a breathing mask further comprising an oxygen saturation sensor extended from the mask. Miles does teach an oxygen saturation sensor **5** but the oxygen saturation sensor of Miles is placed on a finger rather than extending from the mask (See Fig. 2). However, Miles also teaches that some of the sensors may be mounted inside or connected to the mask (**See Col. 4**, **lines 44-45**). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including an oxygen saturation sensor, may be placed inside the mask or connected to the mask thereby reading on the limitation "extended from the mask" and thus providing an alternative placement of the sensor.

Art Unit: 3743

13. As to claim 61, the above combination teaches essentially all of the limitations except for wherein the perimeter surface is adapted to detect eye movement. Miles does teach a sensor that detects eye movement (See Col. 4, lines 33-37). Miles also teaches that some of the sensors may be mounted inside or connected to the mask (See Col. 4, lines 44-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including a sensor that detects eye movement, may be placed inside the mask or connected to the mask (a perimeter surface is encompassed by the disclosure) to provide an alternative placement of the sensor.

Page 7

14. As to claim 77, Miles teaches a breathing mask 3,26 for monitoring a patient during gas delivery comprising a body (See Fig. 2 attachment above) having an internal surface (inherent from Fig. 2 attachment above since mask is shown to be cupping the nose), an external surface (See Fig. 2 attachment above), and a perimeter surface (See Fig. 2 attachment above) shaped to form a seal around the patient's nose; and at least one EEG sensor (See Col. 4, lines 33-35; lines 44-45; lines 55-59; Col. 5, lines 6-15; and Col. 7, lines 37-51 which disclose a plurality and variety of sensors including an EEG sensor and further teach that the sensors may be mounted inside the mask or connected to the mask and therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to couple the EEG sensor to the body as providing an alternative placement for the sensors, which sensor would be capable of being positioned on a top portion of a patient's head upon application of the body to a patient).

Art Unit: 3743

Miles teaches essentially all of the limitations except for a headgear adapted to retain the body on the patient's head, the headgear having at least one EEG sensor positioned thereon. Brown teaches the use of a headgear with sensors placed strategically thereon so that the particular bodily condition of the user may be sensed. Therefore, it would have been obvious to one of ordinary skill in the art to provide a headgear in the breathing mask of Miles so that specific body sensors such as an EEG sensor may be placed strategically on the appropriate anatomy of the human being to sense that specific bodily condition as taught by Brown. Furthermore, it would have been obvious to one of ordinary skill in the art that an EEG sensor be placed on or near the head to detect the appropriate signal and as such it would have been further motivation to provide the EEG sensor on a headgear type device to hold the sensors in place in conjunction with the mask.

- 15. Claims 62-66, 68, 69, 70, 71, 73, 74, 75, 76, 79-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles (US 5,353,788) in view of Brown (US 6,000,395).
- 16. As to claim 62, Miles teaches a nasal ventilation mask 3,26 comprising a body (See Fig. 2 attachment above) having an internal surface (inherent from Fig. 2 attachment above since mask is shown to be cupping the nose), an external surface (See Fig. 2 attachment above), and a perimeter surface (See Fig. 2 attachment above) adapted to form a seal around a patient's nose (See Fig. 2 attachment above), an air hose 2 extending from the body; and at least one EMG sensor (chin) (See Col. 7, lines 39-40). It should be noted that Miles also teaches that

Art Unit: 3743

that some of the sensors may be mounted inside or connected to the mask (See Col.

Page 9

4, lines 44-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including an EMG (chin) sensor, may be placed inside the mask or connected to the mask thereby providing an alternative placement of the sensor and thus be capable of detecting muscle activity relating to a sleep state as recited. Miles teaches essentially all of the limitations except for a headgear adapted to retain the body on the patient's head, the headgear having at least one EEG sensor positioned thereon. Brown teaches the use of a headgear with sensors placed strategically thereon so that the particular bodily condition of the user may be sensed. Therefore, it would have been obvious to one of ordinary skill in the art to provide a headgear in the breathing mask of Miles so that specific body sensors such as an EEG sensor may be placed strategically on the appropriate anatomy of the human being to sense that specific bodily condition as taught by Brown. Furthermore, it would have been obvious to one of ordinary skill in the art that an EEG sensor be placed on or near the head to detect the appropriate signal and as such it would have been further motivation to provide the EEG sensor on a headgear type device to hold the sensors in place in conjunction with the mask.

As to claim 63, Miles teaches essentially all of the limitations including a first 17. sensor for detecting nasal breathing (See Col. 5, lines 12-14) and a second sensor for detecting oral breathing (See Col. 7, lines 41-42) except for the location of the sensors. It should be noted that Miles also teaches that that some of the sensors may be mounted inside or connected to the mask (See Col. 4, lines 44-45). Therefore, it

Art Unit: 3743

would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors may be placed inside the mask or connected to the mask thereby providing an alternative placement for the sensors.

- 18. As to claim 64, Miles teaches a mask wherein the first and second sensors are thermal sensors (See Col. 5, lines 12-14 and See Col. 7, lines 41-42).
- 19. As to claim 65, Miles teaches essentially all of the limitations including an EEG sensor (See Col. 4, lines 33-35; lines 55-59; Col. 5, lines 6-15; and Col. 7, lines 37-51) except for the EEG sensor positioned on the perimeter surface. However, Miles also teaches that some of the sensors may be mounted inside or connected to the mask (See Col. 4, lines 44-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including an EEG sensor, may be placed inside the mask or connected to the mask (a perimeter surface is encompassed by the disclosure) to provide an alternative placement of the sensor.
- 20. As to claim 66, Miles teaches essentially all of the limitations including an EOG sensor (See Col. 4, lines 36-37; lines 55-59; and Col. 7, line 39) except for the EOG sensor positioned on the perimeter surface. However, Miles also teaches that some of the sensors may be mounted inside or connected to the mask (See Col. 4, lines 44-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including an EOG sensor, may be placed inside the mask or connected to the mask (a perimeter

Art Unit: 3743

surface is encompassed by the disclosure) to provide an alternative placement of the sensor.

- 21. **As to claim 68**, Miles teaches essentially all of the limitations including a plurality of straps (**See Fig. 2**) except for the straps having at least one sensor positioned thereon. However, Miles also teaches that some of the sensors may be mounted inside or connected to the mask (**See Col. 4**, **lines 44-45**). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, may be placed inside the mask or connected to the mask (the straps being connected to the mask) to provide an alternative placement of the sensor.
- 22. As to claim 69, Miles teaches essentially all of the limitations including a position sensor (See Col. 4, line 58 which discloses overall physical movement which the Examiner considers equivalent to a position sensor since a position sensor would detect any movement or lack thereof; See also Col. 7, lines 46-49) except for the position sensor positioned on the perimeter surface. However, Miles also teaches that some of the sensors may be mounted inside or connected to the mask (See Col. 4, lines 44-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including a position sensor, may be placed inside the mask or connected to the mask to provide an alternative placement of the sensor.
- 23. As to claim 70, Miles teaches essentially all of the limitations including a microphone 10 (See also Col. 7, lines 42-43) except for the microphone coupled to the

Art Unit: 3743

body. However, Miles also teaches that some of the sensors may be mounted inside or connected to the mask (See Col. 4, lines 44-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including a microphone which would sense breathing and snoring, may be placed inside the mask or connected to the mask to provide an alternative placement of the microphone.

- As to claim 71, Miles teaches essentially all of the limitations including a sensor to detect air leaks (Please note, Col. 4, lines 35-36 and line 56; Col. 5, lines 22-31; and Col. 7, lines 41-44 teach an airflow sensor and a pressure sensor which would indirectly sense air leaks should there be a pressure drop which would also effect the airflow) except for the location of such a sensor on the perimeter surface. However, it should be noted that Miles also teaches that some of the sensors may be mounted inside or connected to the mask (See Col. 4, lines 44-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including one senses air leaks via a airflow sensor or pressure sensor, may be placed inside the mask or connected to the mask (a perimeter surface is encompassed by the disclosure) to provide an alternative placement of the sensor.
- 25. As to claim 73, Miles teaches a nasal ventilation mask 3,26 (See Fig. 2 attachment above) adapted to form a seal around a patient's nose (See Fig. 2 attachment above), an EEG sensor (See Col. 4, line 59 and Col. 7, line 39). Miles teaches essentially all of the limitations except for a headgear adapted to retain the

Page 13

Art Unit: 3743

body on the patient's head, the headgear having at least one EEG sensor positioned thereon. Brown teaches the use of a headgear with sensors placed strategically thereon so that the particular bodily condition of the user may be sensed. Therefore, it would have been obvious to one of ordinary skill in the art to provide a headgear in the breathing mask of Miles so that specific body sensors such as an EEG sensor may be placed strategically on the appropriate anatomy of the human being to sense that specific bodily condition as taught by Brown. Furthermore, it would have been obvious to one of ordinary skill in the art that an EEG sensor be placed on or near the head to detect the appropriate signal and as such it would have been further motivation to provide the EEG sensor on a headgear type device to hold the sensors in place in conjunction with the mask.

- 26. As to claim 74, Miles teaches a mask 3,26 furthering comprising a computer 25 in communication with the sensor, the computer adapted to determine arousal (See Col. 4, lines 32-66; please note the Examiner considers overall physical movement, leg movement, eye movement, EEG all to detect some form of arousal).
- 27. As to claim 75, Miles teaches a mask 3,26 furthering comprising a computer 25 in communication with the sensors, the computer adapted to determine sleep state (See Col. 4, lines 32-66; please note the Examiner considers breathing sounds, overall physical movement, leg movement, eye movement, EEG, sleep position all to detect some form of sleep state).

Art Unit: 3743

28. As to claim 76, Miles teaches a mask further comprising an EMG sensor (chin) (See Col. 7, lines 39-40). Miles does not explicitly teach the EMG sensor coupled to the nasal mask. However, it should be noted that Miles also teaches that that some of the sensors may be mounted inside or connected to the mask (See Col. 4, lines 44-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including an EMG (chin) sensor, may be placed inside the mask or connected to the mask thereby providing an alternative placement of the sensor.

Page 14

29. As to claim 79, Miles teaches a nasal ventilation system comprising a nasal mask 3,26 for monitoring a patient during gas delivery comprising a body (See Fig. 2 attachment above) having an internal surface (inherent from Fig. 2 attachment above since mask is shown to be cupping the nose), an external surface (See Fig. 2 attachment above) shaped to form a seal around the patient's nose; and at least one EEG sensor (See Col. 4, lines 33-35; lines 44-45; lines 55-59; Col. 5, lines 6-15; and Col. 7, lines 37-51 which disclose a plurality and variety of sensors including an EEG sensor and further teach that the sensors may be mounted inside the mask or connected to the mask and therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to couple the EEG sensor to the body as providing an alternative placement for the sensors, which sensor would be capable of being positioned on a top portion of a patient's head upon application of the body to a patient), an EMG sensor (See Col. 7, lines 39-40) located on the perimeter surface,

Art Unit: 3743

and a computer 25 in communication with the EEG and EMG sensor, the computer adapted to determine sleep state (See Col. 4, lines 32-66; please note the Examiner considers breathing sounds, overall physical movement, leg movement, eye movement, EEG, sleep position all to detect some form of sleep state). Miles teaches essentially all of the limitations except for a headgear adapted to retain the body on the patient's head, the headgear having at least one EEG sensor positioned thereon. Brown teaches the use of a headgear with sensors placed strategically thereon so that the particular bodily condition of the user may be sensed. Therefore, it would have been obvious to one of ordinary skill in the art to provide a headgear in the breathing mask of Miles so that specific body sensors such as an EEG sensor may be placed strategically on the appropriate anatomy of the human being to sense that specific bodily condition as taught by Brown. Furthermore, it would have been obvious to one of ordinary skill in the art that an EEG sensor be placed on or near the head to detect the appropriate signal and as such it would have been further motivation to provide the EEG sensor on a headgear type device to hold the sensors in place in conjunction with the mask.

Page 15

30. **As to claim 80**, the above combination teaches a system further comprising a gas delivery system in communication with the computer and coupled to the mask. As to the recitation of "pneumatically," it should be noted that in a device/apparatus claim, patentable weight is given to the end product not the process. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its

method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

- 31. **As to claim 81**, the above combination teaches a system wherein an output of the gas delivery system is controlled by the patient's sleep state.
- 32. As to claim 82, the above combination teaches a system further comprising a sensor located on the external surface for determining if a patient is breathing through his mouth. (See Col. 4, lines 33-35; lines 44-45; lines 55-59; Col. 5, lines 6-15; and Col. 7, lines 37-51 which disclose a plurality and variety of sensors and further teach that the sensors may be mounted inside the mask or connected to the mask).
- 33. As to claim 83, the above combination teaches a system further comprising a flow sensor located on the internal surface. (See Col. 4, lines 33-35 and Col. 5, lines 20-21). It should be noted that in Col. 5, lines 20-21, Miles teaches a flow sensor contained within the CPAP device; however, Miles also teaches that some of the sensors may be mounted inside or connected to the mask (See Col. 4, lines 44-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including a flow sensor, may be placed inside the mask or connected to the mask thereby providing an alternative placement of the sensor.

Art Unit: 3743

34. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miles (US 5,353,788) in view of Brown (US 6,000,395) and further in view of Bornn (US 5,353,793).

- 35. **As to claim 67**, Miles and Brown teach essentially all of the limitations except for wherein a portion of the perimeter is comprised of a conductive carbonized rubber material. It should be noted that Bornn does teach the use of physiological sensors such as ECG, piezoelectric sensors for monitoring respiration and pulse, temperature sensors, and activity and position sensor, which come into contact with the patient's skin. Bornn further provides a conductive carbonized rubber material (**See Col. 7, lines 34-37 of Bornn**) for providing electrical contact between a person's skin and the sensor. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a portion of the perimeter surface with a conductive carbonized rubber material as taught by Bornn to provide an electrical contact between a person's skin and the sensor since Miles discloses that the sensors may be mounted inside the mask (which would include a portion of the perimeter surface).
- 36. Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miles (US 5,353,788) in view of Brown (US 6,000,395) and further in view of Wiesmann et al (US 6,199,550).
- 37. **As to claim 72**, Miles and Brown teach essentially all of the limitations except for the mask further comprising a patient recycled air detection system positioned on the internal surface. Wiesmann et al teaches a mask with sensors including a sensor which monitors exhaled carbon dioxide (**See Col. 5**, **line 42**) located on the internal surface of

Application/Control Number: 09/465,054 Page 18

Art Unit: 3743

the mask (See Fig. 3 of Wiesmann et al). It should be noted that the sensor of Wiesmann et al is equivalent in scope to the recycled air detection system of Applicant since Applicant on page 10 of the specification discloses that the air detection system has a sensor that detects the amount of expired air from the patient remaining in the mask. The Wiesmann et al sensor monitors the exhaled carbon dioxide and would also indirectly detect any remaining exhaled air in the mask since the Wiesmann sensor is located on the interior of the mask. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a sensor that monitors exhaled carbon dioxide in the mask of Miles as taught by Wiesmann et al so that the amount of air exhaled by the patient would be detected by the sensor and indirectly measure the exhaled air remaining in the mask.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 571-272-4802. The examiner can normally be reached on Monday-Friday (11:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3743

Page 19

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mital B. Påtel Primary Examiner Art Unit 3743